

611. Misbranding of Bron-Chu-Line Emulsion. U. S. v. 21 Bottles of Bron-Chu-Line Emulsion. Default decree of condemnation and destruction. (F. D. C. No. 5928. Sample No. 42975-E.)

In addition to failure to bear adequate warning statements, the labeling of this product contained false and misleading claims regarding its efficacy in the conditions indicated hereinafter.

On September 30, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against the above-named product at Pittsburgh, Pa., alleging that the article had been shipped in interstate commerce on or about July 17, 1941, by the Johnstone Drug Sales Corporation from Rochester, N. Y.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of creosote, calcium, sodium and phosphorus compounds, benzyl alcohol, methyl salicylate, and gum acacia emulsified in a mineral oil.

It was alleged to be misbranded in that the statements in the labeling, "Bron-Chu-Line * * * Antispasmodic * * * of rare value in the treatment of irritated conditions of the respiratory passages * * * Beechwood Creosote possess values as an anti-pathogen, equal to if not superior to carbolic acid, and has long been considered of superior worth where any tubercular tendency is involved. * * * Methyl Salicylate acts as an eliminant of urea, uric acid and other acid waste matter whose excess presence is detrimental to recovery, such an excess of waste acid matter being a common presence where coughs, colds and catarrhal conditions are persistent; * * * Calcium and Sodium Hypophosphites are reconstructive tonics. In respiratory affections there is a constant waste of these vital body salts through expectoration. Such waste lowers body resistance and the presence of these Hypophosphites in the prescription is to afford resupply for body need. * * * We especially recommend Bron-Chu-Line Emulsion in such cases that the usual lozenge or home remedy has failed to relieve," were false and misleading since they indicated that it was of value in conditions involving the bronchi or lungs; whereas it was of no such value since it was essentially an expectorant and was not an antispasmodic, and it was not of real value in the treatment of irritated conditions of the respiratory passages; Beechwood Creosote was not present in sufficient quantity to be an anti-pathogen, and methyl salicylate was not present in the article in sufficient quantity to be an eliminant of urea, uric acid, and other acid waste matter when used as directed, and urea, uric acid, and other waste matter are not commonly present in excess where coughs, colds, and catarrhal conditions are persistent; calcium and sodium hypophosphites are not reconstructive tonics; there is not a constant waste through expectoration of calcium and sodium hypophosphites in respiratory affections; calcium and sodium hypophosphites are not vital body salts; and waste of calcium and sodium hypophosphites does not lower body resistance; and the product would not be efficacious in cases in which the usual lozenge or home remedy had failed to provide relief. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions such as persistent cough or high fever where its use might be dangerous to health, or against unsafe duration of administration, since the duration of administration was not limited to 10 days, nor was the warning in such manner and form as is necessary for the protection of users.

On November 25, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

612. Misbranding of Ches-O-Kol. U. S. v. 199 Pounds of a Drug and 16 Dozen Packages of the same drug labeled "Ches-O-Kol." Default decree of condemnation and destruction. (F. D. C. No. 4896. Sample No. 37049-E.)

The drum in which this product was shipped failed to bear adequate directions for use and a statement of the common or usual name of the active ingredients. A portion had been repackaged in jars and cartons which bore on the labels false and misleading curative and therapeutic claims.

On June 24, 1941, the United States attorney for the Western District of South Carolina filed a libel against a drum containing 199 pounds and 16 dozen packages of Ches-O-Kol at Spartanburg, S. C., alleging that the article originally had been shipped on or about January 21, 1941, by the William A. Webster Co. from Memphis, Tenn., and that a portion (16 dozen packages) had been repackaged in 1½-ounce bottles and was in possession of the Ches-O-Kol Co., Spartanburg, S. C.; and charging that both lots were misbranded.

Analysis showed that the article consisted essentially of camphor, menthol, eucalyptol, and turpentine in a petrolatum base.